

# Ipsen

## **First Half 2011 Results Roadshow – JP Morgan New York / Boston – 30th August to 2nd September 2011**

*Marc de Garidel – Chairman and Chief Executive Officer*

*Claude Bertrand – EVP – Chief Scientific Officer*

*Pierre Kemula – Investor Relations Officer*

*Stéphane Durant des Aulnois – Investor Relations Manager*



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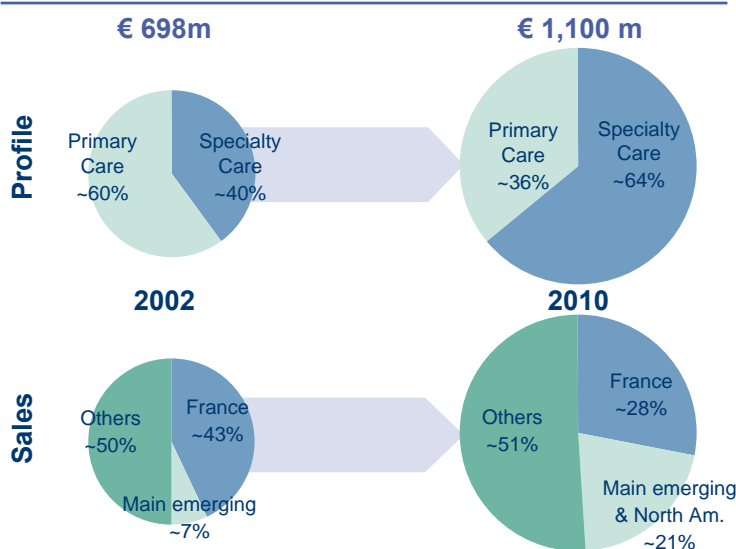
The implementation of the strategy has to be submitted to the relevant staff representation authorities in each country concerned, in compliance with the specific procedures, terms and conditions set forth by each national legislation.

# New Strategy

## Summary

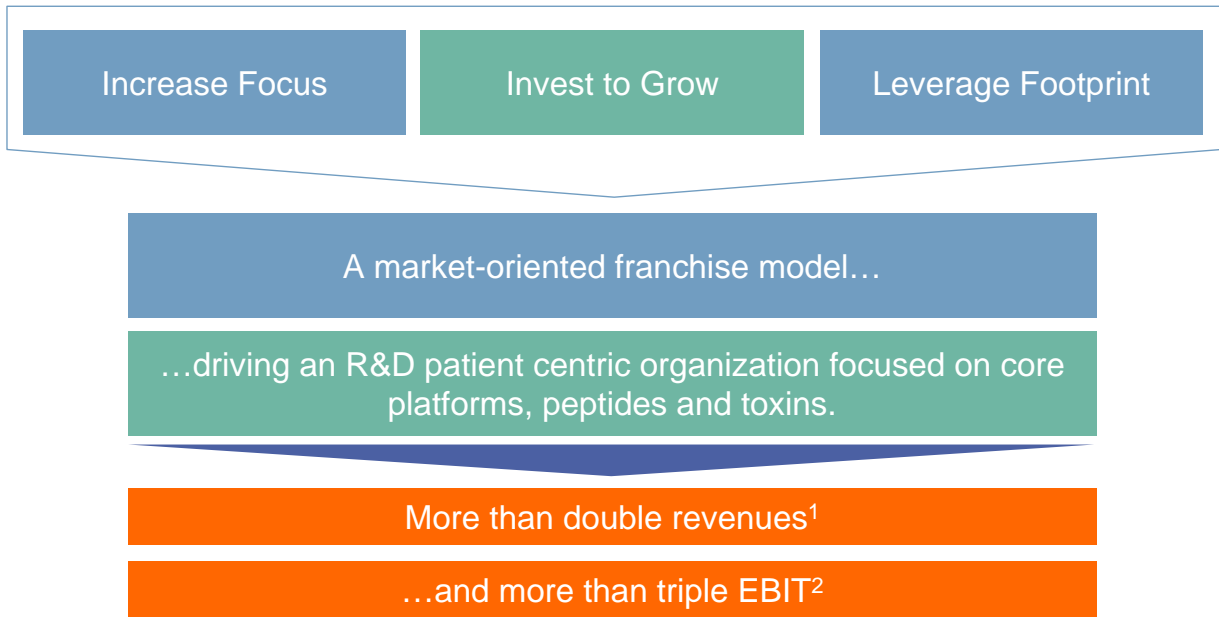
Over the last decade, Ipsen has succeeded in adapting to a fast changing environment

### Evolution of Ipsen's sales profile



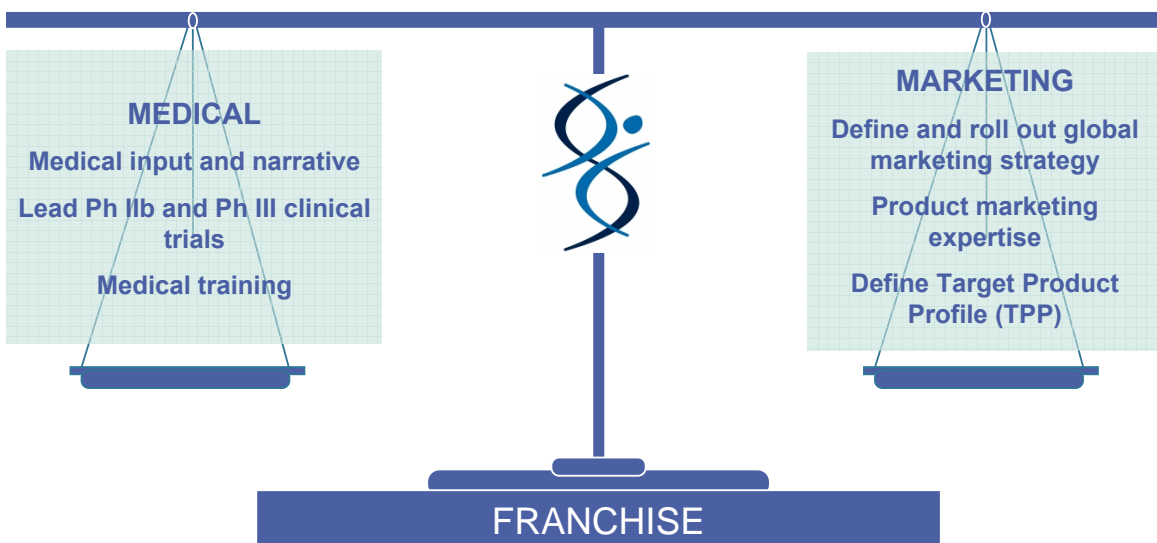
**Ipsen is ideally positioned to benefit from current market trends**

## New strategy aims at leveraging Ipsen's core strengths to become a global leader in targeted debilitating diseases



NOTE 1: 2020 projected figures include contribution of Inspiration portfolio and are set at constant foreign exchange rate  
NOTE 2: prior to purchase accounting recordings and non recurring elements

## Franchise model to bring commercial reality at the center of drug development...



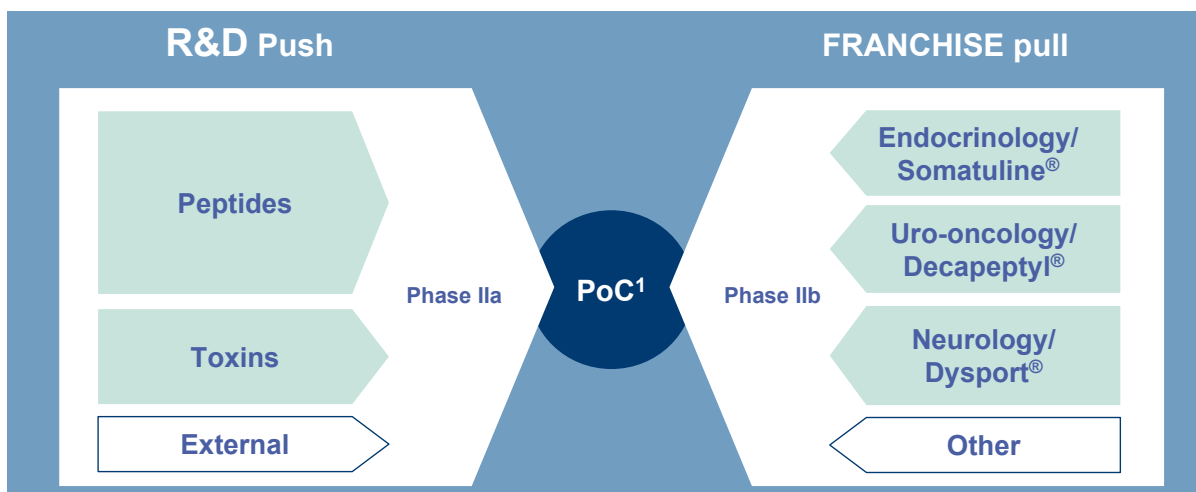
*Countries are responsible for P&L performance*

## ...with differentiated focus along the value chain

	Research	Early dev. (end of PhIIa)	Late dev. (PhIIb & PhIV)	Manufacturing	Operations
Endocrinology/ Somatuline®	✓	✓	✓	✓	✓
Neurology/ Dysport®	✓	✓	✓	✓	✓
Uro-oncology/ Decapeptyl®	✓ Ipsen or Partner	✓ Ipsen or Partner	✓ Ipsen or Partner	✓ Ipsen or Partner	✓
Hemophilia	✓ Partner	✓ Partner	✓ Ipsen or Partner	✓ Ipsen or Partner	✓ Ipsen or Partner

*Primary care and Short Stature in a commercial optimization strategy*

## ...with an integrated R&D “push-pull” model to fulfill patient/ commercial requirements



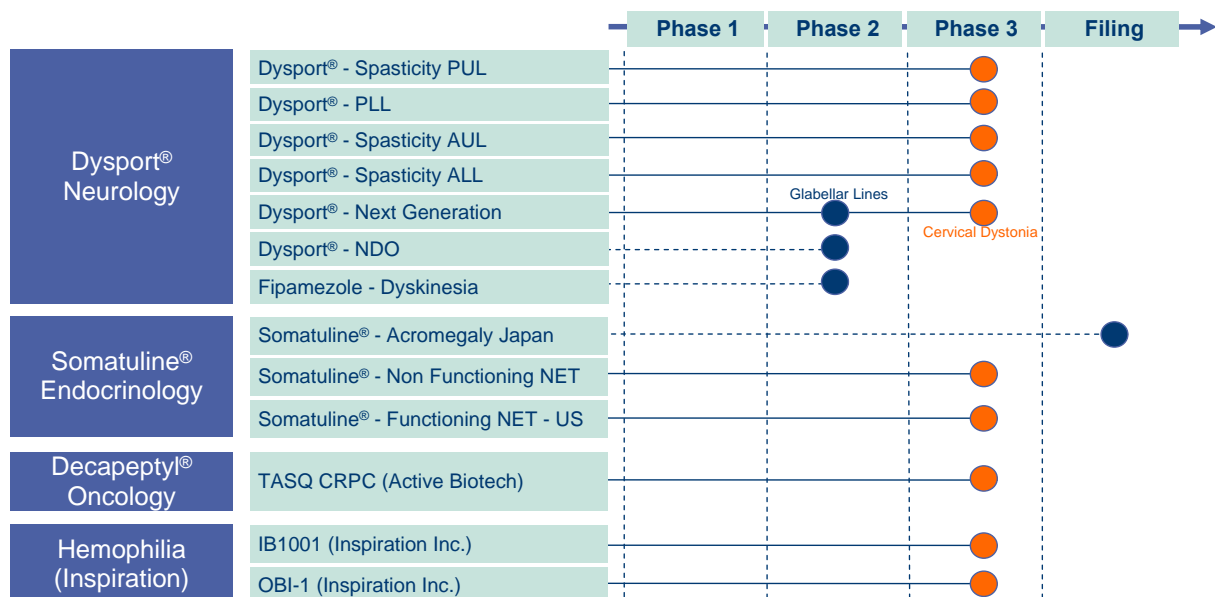
... with key decisions made

## 2020 strategy implies important choices

### Increase focus

- Close R&D activities at **Barcelona** site
- **Terminate one third of R&D** projects
- Regions and countries to manage **Short Stature** in commercial optimization perspective
- Explore new commercial partnership opportunities in **French primary care**
- Ensure sustainable future to **Dreux** manufacturing site

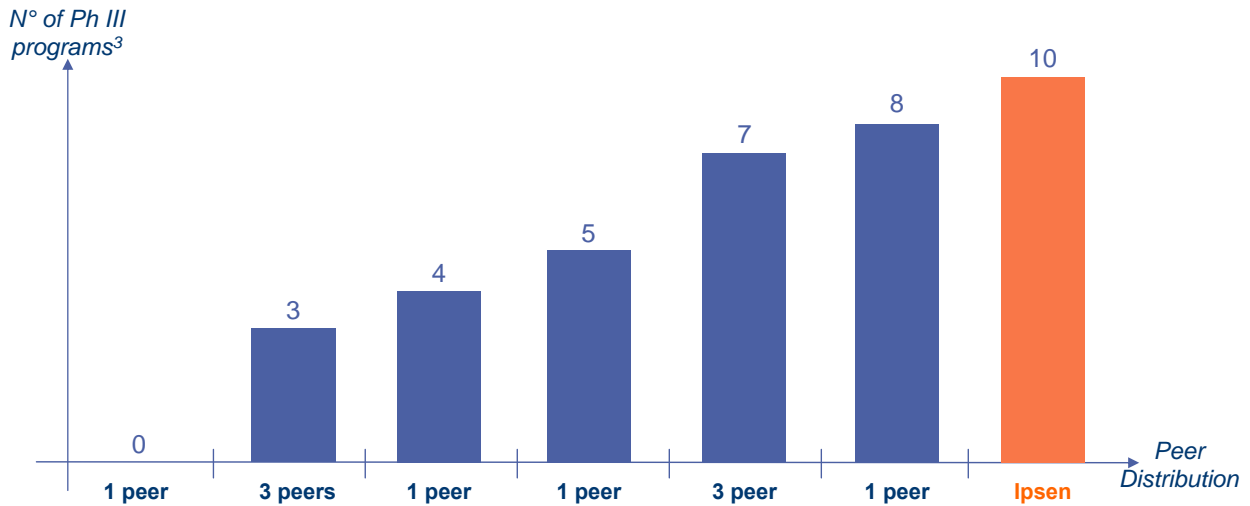
## Invest to grow: a rich Ph III program



10 on-going phase IIIs, 4 for NMEs, 6 for life cycle management

## Ipsen differentiated from 10 peers<sup>1</sup> in terms of Ph III intensity<sup>2</sup>

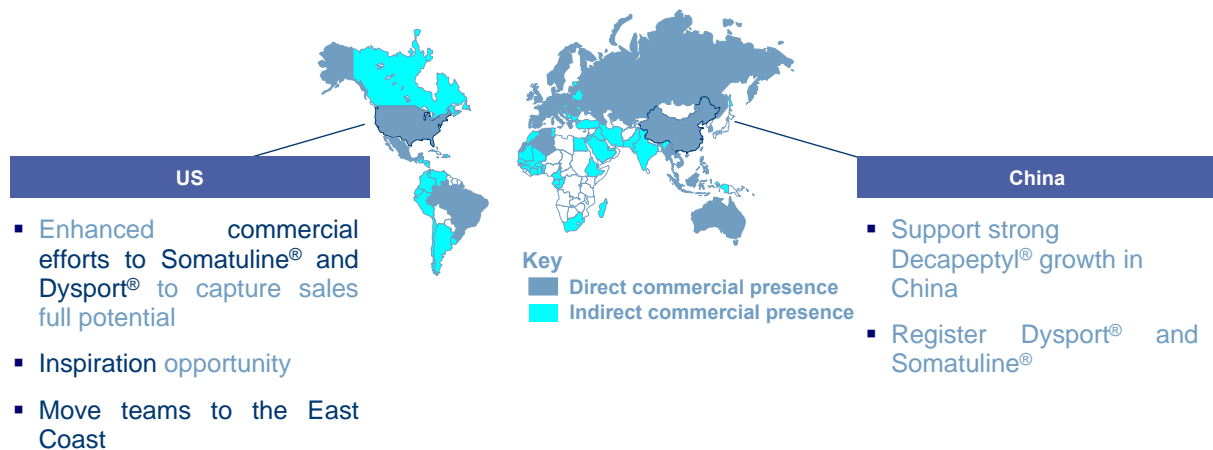
### Ipsen and its peers<sup>1</sup> - Intensity of Ph III programs



NOTE 1 : 10 peers selected with a criteria such as Sales, EBIT, R&D to sales ratio, PE, Headcount, Therapeutic Areas, Geographical reach...  
Peers include: Lundbeck, Meda, Almirall, Shire, Biogen Idec, Allergan, Novo Nordisk, Merck Serono, Actelion and Orion  
NOTE 2 : Based on available and disclosed information as of august 2011  
Note 3 : Number of Ph III for a single indication

## Leverage Ipsen's extensive commercial reach as a major growth driver

### Ipsen recorded sales in 115 in 2010

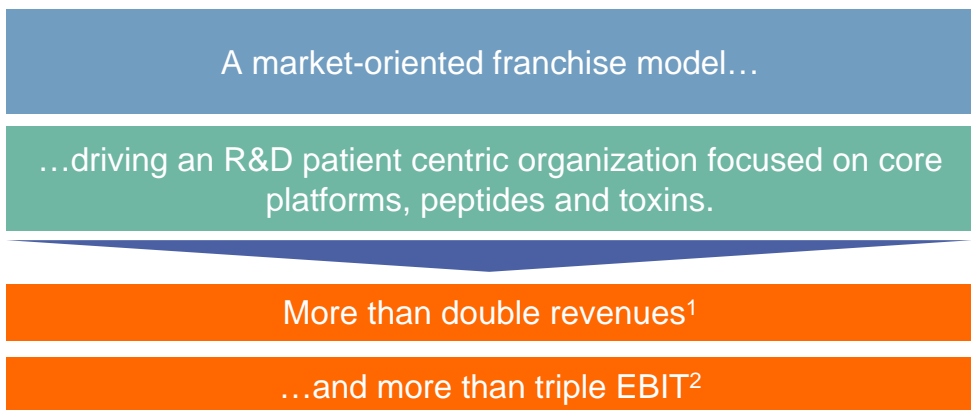
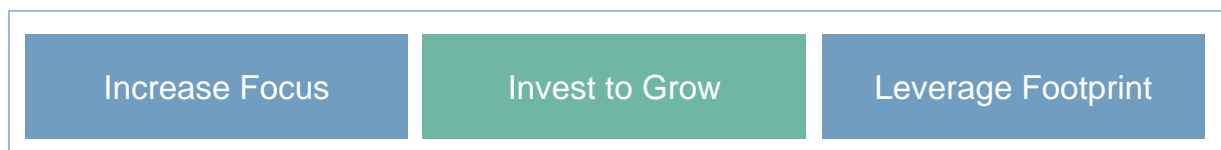


Further leverage Ipsen's profitable commercial reach

## Group strategy – Execution on track



### Ipsen's 2020 aspiration: Become a global leader in targeted debilitating diseases



## Implementation: main milestones to success

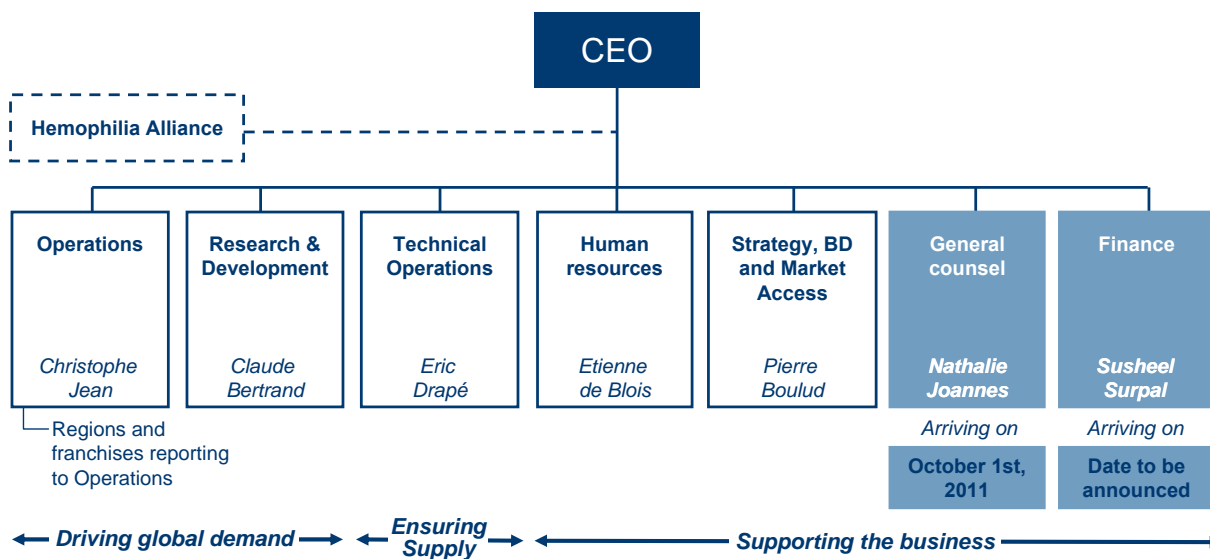
2011	2012	2013	2014	2015 →
<input checked="" type="checkbox"/> Define strategy	<input type="checkbox"/> R&D « PoC » machine implemented	<input type="checkbox"/> Somatuline® New device rolled out globally	<input type="checkbox"/> TASQ filed in Europe	<input type="checkbox"/> Inspiration option assessment
<input type="checkbox"/> Merge R&D	<input type="checkbox"/> Barcelona R&D site closed	<input type="checkbox"/> Dysport® A. & P. L.L spasticity filed	<input type="checkbox"/> Somatuline® F. NET filed in the US	<input type="checkbox"/> Dysport® P.U.L filed in the US
<input checked="" type="checkbox"/> Reinforce Uro-oncology franchise (TASQ)	<input type="checkbox"/> French primary care commercial activities partnered	<input type="checkbox"/> Dysport® NDO Ph III initiated	<input type="checkbox"/> Somatuline® NF NET filed WW	<input type="checkbox"/> 5 new Pre clinical candidates (vs. June 2011) O/W 3 reach POC
<input checked="" type="checkbox"/> Dysport® CD CTA <sup>1</sup> filing in China	<input type="checkbox"/> IB1001 filed in the USA	<input type="checkbox"/> Smecta® EDL assessment (China)	<input type="checkbox"/> Dysport® A.U.L filed	<input type="checkbox"/> Smecta® EDL assessment (China)
<input checked="" type="checkbox"/> Somatuline® Acromegaly CTA <sup>1</sup> filing in China	<input type="checkbox"/> OBI-1 PhIII (Acquired H) enrollment completed	<input type="checkbox"/> OBI-1 Acquired H. filed in the US	<input type="checkbox"/> Dysport® NG filed	
<input checked="" type="checkbox"/> New extended Executive Committee staffed	<input type="checkbox"/> OB-1 PhIII Congenital H. initiated		<input type="checkbox"/> Dysport® P.U.L filed in Brazil	
<input type="checkbox"/> Franchise org. implemented	<input type="checkbox"/> US platform reorganized		<input type="checkbox"/> Inspiration option assessment	
<input type="checkbox"/> IB1001 filed in Europe			<input type="checkbox"/> Smecta® EDL assessment (China)	

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NOTE 1: CTA or filing for Clinical Trial Authorization

Subject to the relevant staff representation authorities in each country concerned, in compliance with the specific procedures, terms and conditions set forth by each national legislation

## Executive Committee recruitment completed

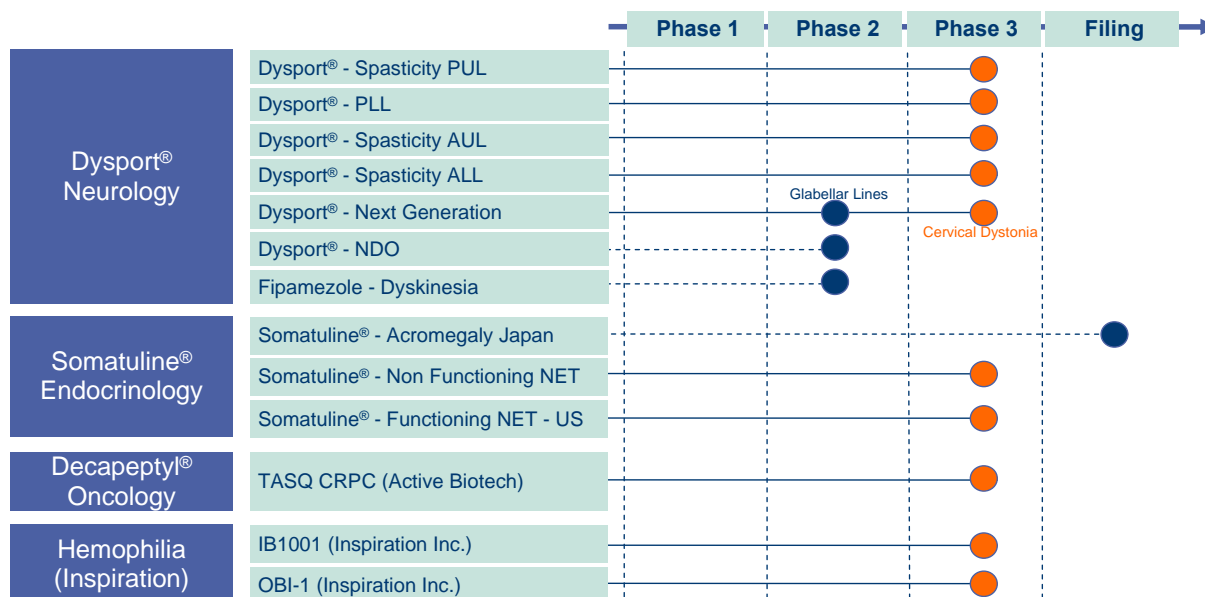




## Progress update

Increase Focus R&D	<ul style="list-style-type: none"> <li>Barcelona R&amp;D site: all administrative and employee-related procedures required to close the R&amp;D are completed</li> </ul>
Footprint US	<ul style="list-style-type: none"> <li>Move to the east coast initiated</li> <li>Target completion date: January 1<sup>st</sup>, 2012</li> </ul>
Other	<ul style="list-style-type: none"> <li>Primary Care France:             <ul style="list-style-type: none"> <li>On-going preliminary contacts with potential partners</li> </ul> </li> <li>Organizational change:             <ul style="list-style-type: none"> <li>On-going discussions with workers council</li> </ul> </li> </ul>

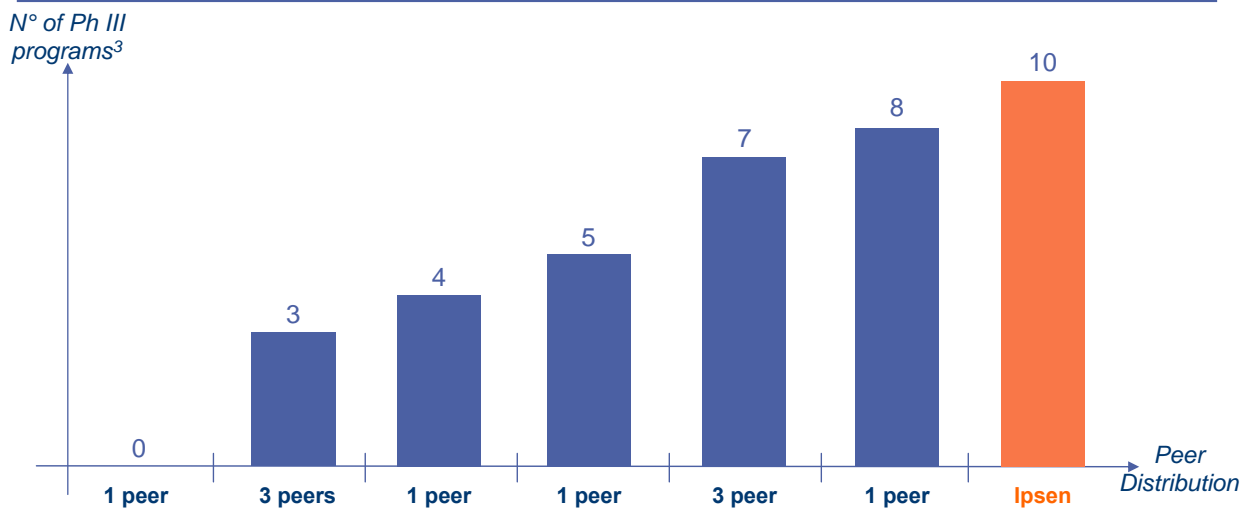
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## Ipsen differentiated from 10 peers<sup>1</sup> in terms of Ph III intensity<sup>2</sup>

Ipsen and its peers<sup>1</sup> - Intensity of Ph III programs



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## Ipsen “new” R&D ambition

*5 novel pre-clinical candidates...*

*...out of which 3 will reach POC decision by end of 2015...*

*...while all life cycle initiatives are achieved on time*

## Leveraging Ipsen's pan European infrastructure for hemophilia

### European partnership signed with Inspiration for the commercialization of IB1001 and OBI-1

- MAA filing in Europe for IB1001 (recombinant Factor IX) in Europe expected before year end
- Ipsen to act as Inspiration's exclusive commercial agent (FIX and OBI-1)
- Business Unit leveraging Ipsen's **existing** resources combined to Inspiration's expertise
- Inspiration to:
  - Book sales
  - Bear all costs
- EBIT neutral for Ipsen:
  - Book SMM costs
  - Book corresponding Other Revenues (re-billing)
- Potentially attractive commercial opportunity:
  - 2008 FIX European market: c.\$380m<sup>1</sup> or c.44% of ww market
  - 2020 FIX European market<sup>1</sup>: c.\$680m<sup>1</sup>

### Exclusive commercial agent in a total of 53 countries



A plug-and-play commercial organization for Inspiration's hemophilia products in Europe, increasing Ipsen's hemophilia market knowledge and presence

## Detailed Financial Results H1 2011

## H1 2011, a strong performance throughout

5.2%<sup>1</sup> drug sales growth, driven by :

- Robust specialty care growth, up 7.9%<sup>1</sup> y-o-y
- Resilient primary care

20.7%<sup>2</sup> reported operating margin, up 15.1% y-o-y

One-off costs related to the implementation of the new strategy (-€38.7m) partly offset by proceeds from the favorable outcome of a litigation (+€17.2m)

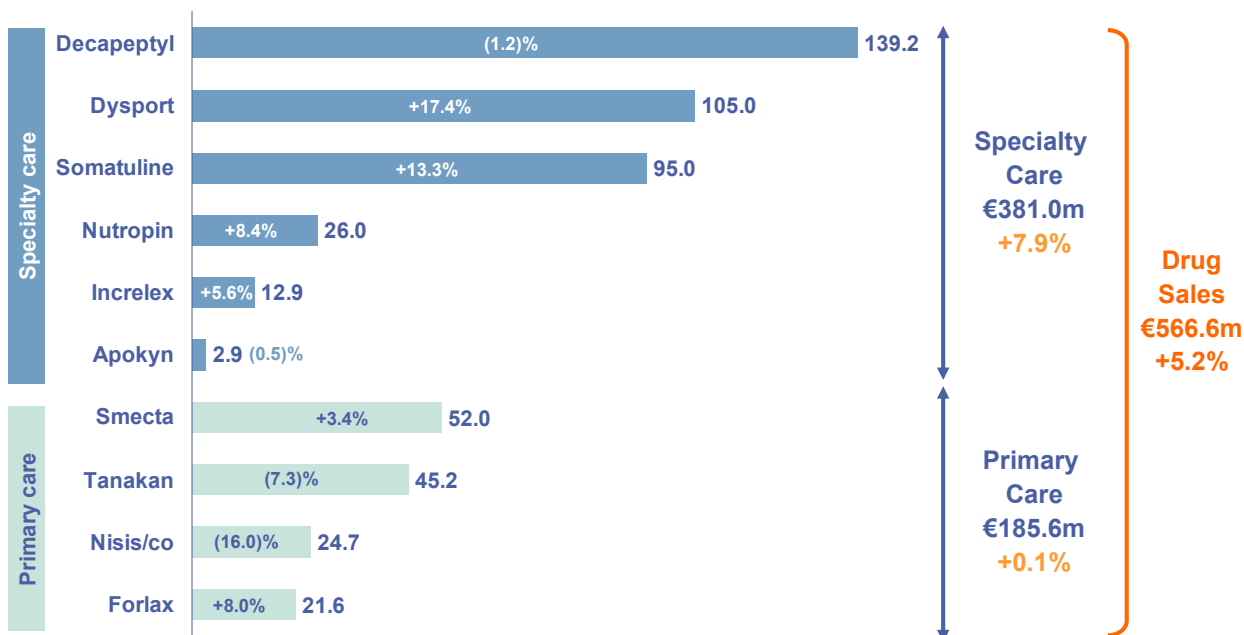
24.7%<sup>2</sup> recurring adjusted<sup>3</sup> operating margin, up 27.1% y-o-y

Recurring adjusted<sup>3</sup> EPS of € 1.27, up 32.3% y-o-y

€132.0m net cash position as at June 30, 2011

## H1 2011 sales: robust specialty care, resilient primary care

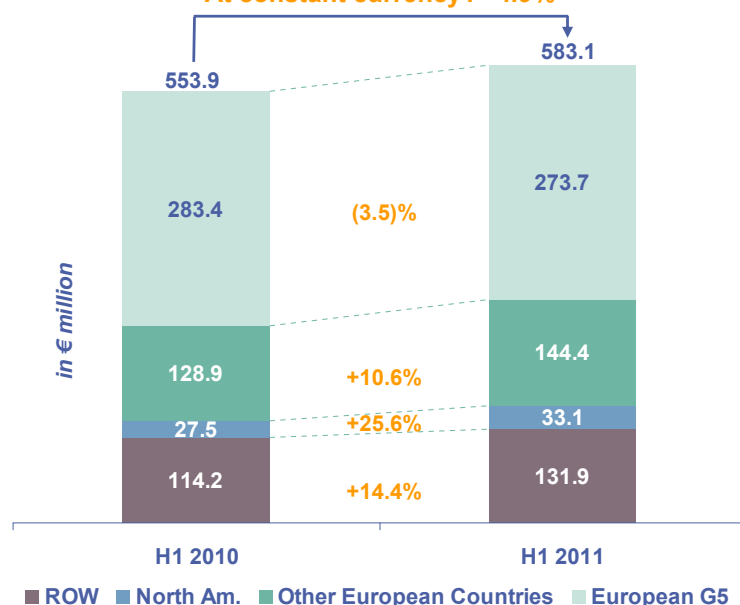
Sales in € million



## Group's Sales driven by regions other than G5

GROUP SALES growth : +5.3% (incl. Drug related sales)

At constant currency : +4.9%



- **European G5**  
Specialty care sales growth offset by tougher competitive environment, notably in French Primary care and government measures in Germany and Spain
- **Other European countries**  
Sustained volume growth, particularly in Switzerland, Russia, Austria and Ukraine
- **North America**  
Continued penetration of Somatuline® and Dysport®
- **ROW**  
Strong volume growth in Algeria, Australia, Columbia and China

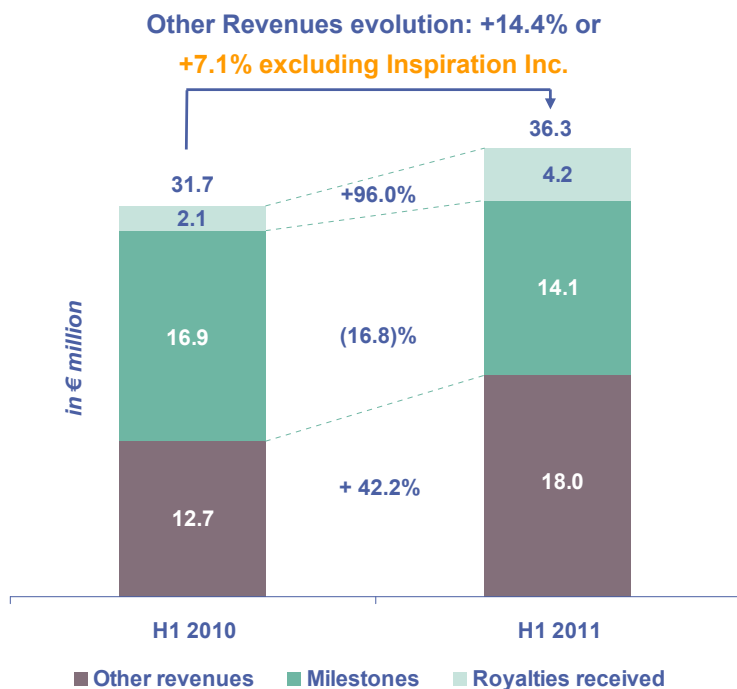
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Growth rates excluding foreign exchange impacts

## Summary of H1 2011 P&L and evolution

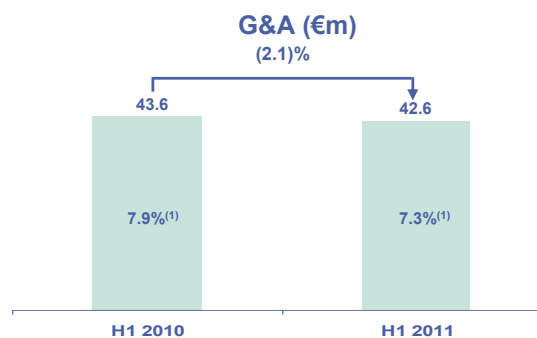
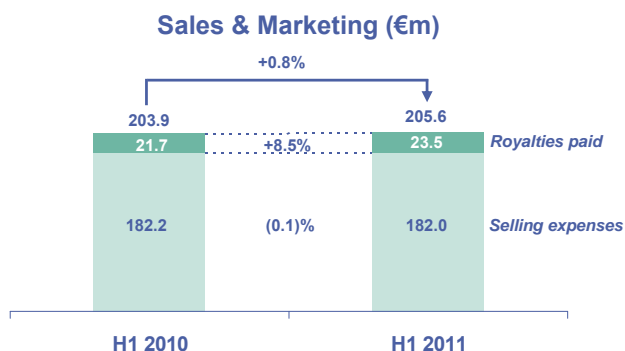
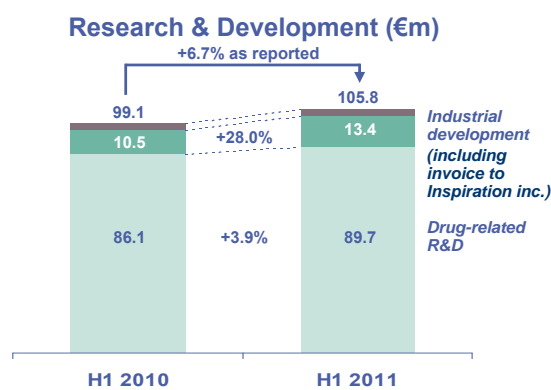
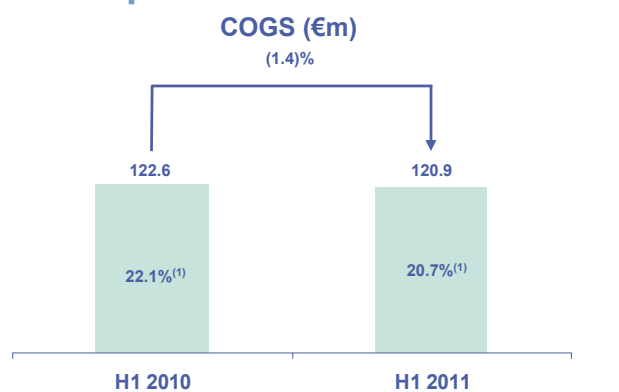
In million euros	H1 2011	H1 2010	Growth (%)
Sales	583.1	553.9	+5.3%
Total Revenues	619.4	585.7	+5.8%
Operating Income <i>Margin<sup>1</sup></i>	120.8 <i>20.7%</i>	104.9 <i>18.9%</i>	+15.1%
Recurring adjusted <sup>2</sup> operating income <i>Margin<sup>1</sup></i>	143.9 <i>24.7%</i>	113.2 <i>20.4%</i>	+27.1%
Consolidated Net Profit <i>(attributable to Ipsen shareholders)</i>	91.7	75.5	+21.4%
Fully diluted EPS	€1.09	€0.90	+21.1%
Fully diluted recurring adjusted <sup>1</sup> EPS	€1.27	€0.96	+32.3%

## Other revenues evolution



- **Royalties Received**  
Royalties received in H1 2011 doubled with increased royalties from Medicis, Galderma and Menarini
- **Milestones**  
Decrease mainly due to accelerated recognition of 2010 taspoglutide Deferred Revenues
- **Other revenues**  
Invoicing of OBI-1's development costs to Inspiration Inc. and income from the Group's Co-promotion contracts in France

## P&L expenses under control



## One-off costs related to the preparation and implementation of the strategy

One-off costs linked to the new strategy announced on June 9

A total of €80m to €100m before tax over 2011 and 2012

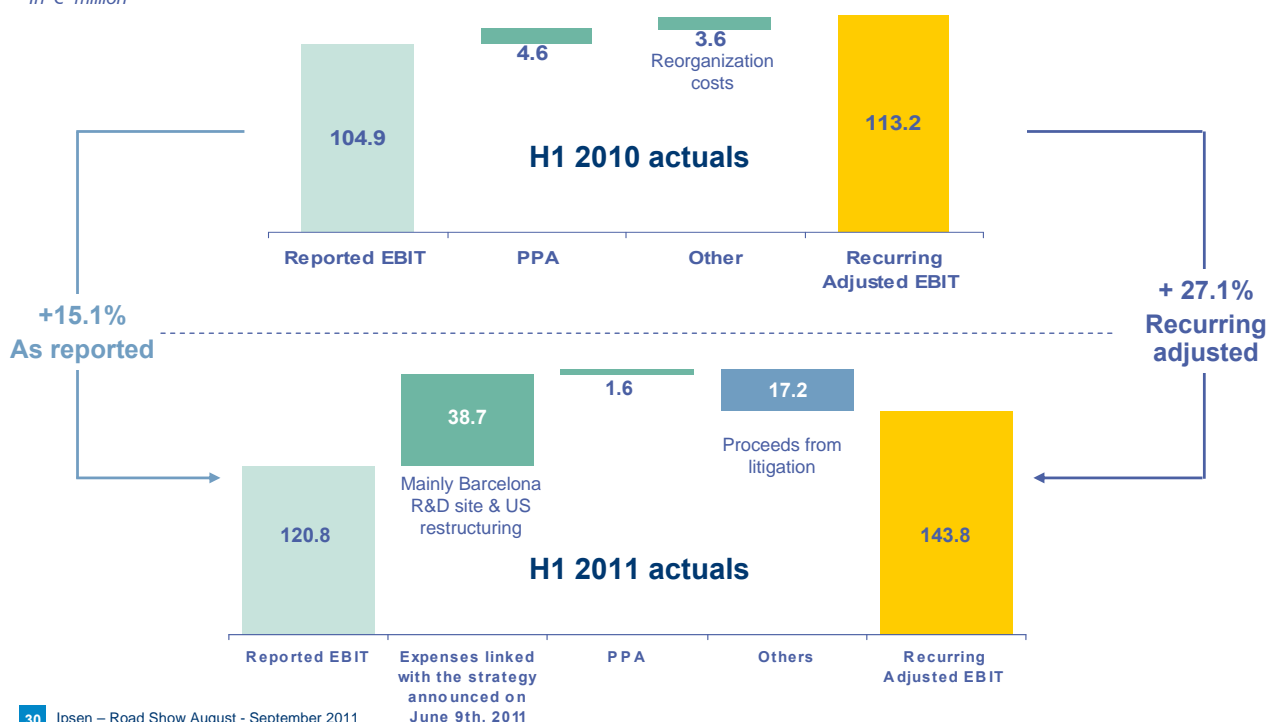
Booked in H1 2011

- USA transfer costs to east coast (€8.7m)
- Closing of R&D activities of Barcelona site (€18.4m)
- Other one-off costs related to the implementation of the strategy and of new organization (€11.6m)

- A total of €38.7m<sup>1</sup> of one-off costs booked in H1 2011
- The balance to be booked over H2 2011 and 2012

## Recurring adjusted<sup>1</sup> Operating Income has improved by 27.1 %

In € million



## P&L – below EBIT



## Balance sheet

In € million

	Assets		Liabilities	
	2010	H1 2011	2010	H1 2011
<b>Goodwill</b>	299.1	290.7	<b>Equity</b>	1 077.2
<b>Investment in associated companies</b> (incl. Goodwill Inspiration Inc.)	57.9	49.4	<b>Minority interests</b>	2.0
<b>Property, Plans &amp; equipments</b>	282.3	275.2	<b>Total Equity</b>	1 079.2
<b>Intangible assets</b>	166.5	182.7	<b>Long-term financial debts</b>	15.3
<b>Other non-current assets</b>	232.6	253.0	<b>Other non-current liabilities</b>	250.6
<b>Total non-current assets</b>	1 038.4	1 050.9	<b>Other current liabilities</b>	324.7
<b>Total current assets</b>	639.8	624.5	<b>Short-term debts</b>	7.7
<i>Incl. Cash and cash equivalent</i>	178.1	159.6	<b>Liabilities / discontinued operations</b>	0.7
<b>Discontinued operations</b>	-	-	<b>Total Liabilities</b>	1 678.2
<b>Total assets</b>	1 678.2	1 675.5		1675.5
<b>Net Cash</b>	156.0	132.0		



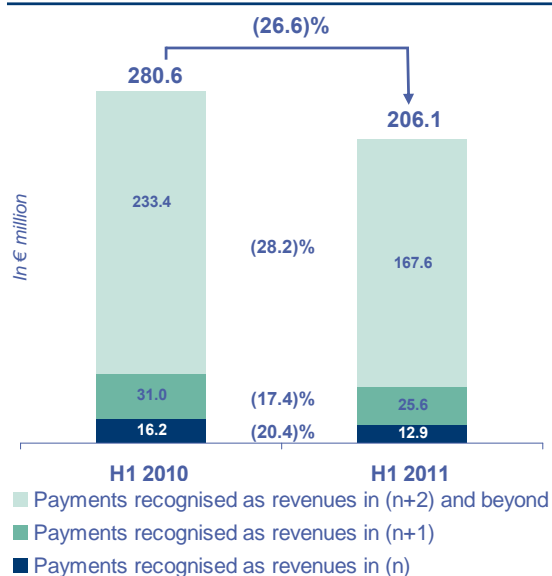
## Cash flow statement

In million euros

	H1 2010	H1 2011
<b>Cash Flow before change in working capital</b>	<b>98.6</b>	<b>123.8</b>
Deferred revenues from partnerships	53.1	3.7
Increase/ Decrease in working capital	(17.0)	(30.2)
<b>Net cash flow generated by operating activities</b>	<b>134.7</b>	<b>97.3</b>
Investment in Tangible and Intangible assets	(25.5)	(44.2)
Investment in Inspiration	(57.6)	-
Subscription in Inspiration's bonds	(35.5)	(0.8)
Others	(5.6)	(3.1)
<b>Net cash flow used in investing activities</b>	<b>(124.3)</b>	<b>(48.1)</b>
Net change in borrowings	(0.2)	(0.2)
Dividends paid	(62.3)	(66.5)
Others	(1.0)	(0.4)
<b>Net cash flow used in financing activities</b>	<b>(63.4)</b>	<b>(67.1)</b>
Discontinued operations	(0.0)	-
<b>Change in cash and cash equivalent</b>	<b>(53.0)</b>	<b>(17.9)</b>
Impact of exchange rate fluctuations	11.7	(5.0)
<b>Closing cash &amp; cash equivalents</b>	<b>164.1</b>	<b>155.0</b>
<b>Closing Net Cash</b>	<b>142.1</b>	<b>132.0</b>

## Deferred revenues

### Total Milestones cashed-in and not yet recognized as revenues



### Main evolutions

- 2010: accelerated recognition of the remaining taspoglutide deferred revenues from Roche
- H1 2010: important milestones revenue from Inspiration (\$50m) and Menarini (€18m)

## FY 2011 Outlook and Newsflow



### Revised 2011 financial objectives

March 2011	Specialist Care Drug sales	Drug Sales growth close to + 8.0% year-on-year
	Primary Care Drug sales	Drug sales decrease of (8.0%) to (10.0%) year-on-year, pending evolution in France
August 2011	Specialist Care Drug sales	Drug Sales growth close to + 8.0% year-on-year
	Primary Care Drug sales	Drug sales decrease of (3.0%) to (5.0%) year-on-year
	Recurring Adjusted <sup>1</sup> operating income	Ranging from €190 million to €200 million

The above objectives are set at constant currency  
2011 objective excludes any potential non recurring items

## News flow – upcoming catalysts

Filing of IB1001 in Europe (H2 2011) and in the US (H1 2012)

Implementation<sup>1</sup> of Franchise based organization

New future for Primary Care France and Dreux manufacturing plant

Maximize value of Apokyn<sup>®</sup> and Increlex<sup>®</sup> in the US while meeting its obligations to patients and partners

New US platform fully operational

## H1 2011: key take-aways

2011, a year of transition...

...with a strong H1 financial performance...

...despite one-off restructuring costs...

...related to the implementation of the new strategy...

...and an increased drug sales objectives



# Appendices



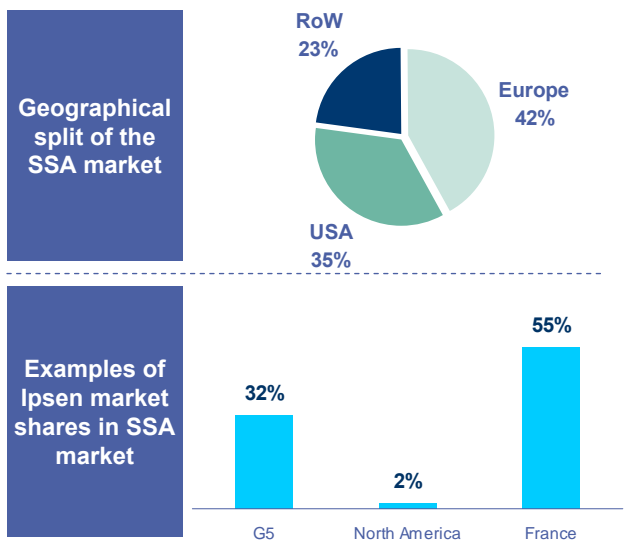
***Zoom on***

***Endocrinology/ Somatuline<sup>®</sup>***



## Global Somatostatin Analog (SSA) market in 2010 : ~ 1.1 billion euros...

### Q4, 2010 market figures

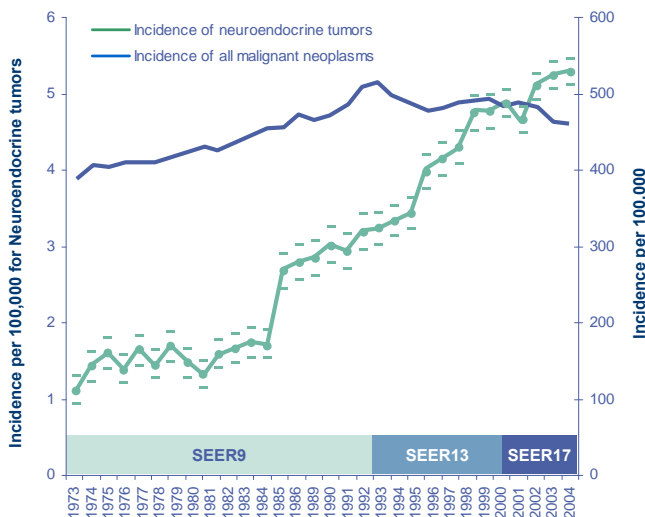


- 2010 SSA market: ~€ 1.1bn
- Solid SSA market growth (+9%<sup>1</sup> in 2009 and +18%<sup>1</sup> in 2010)
- A fairly balanced geographical split between Europe (42% of total sales), the US (35%) and the RoW (23%)
- Somatuline<sup>®</sup>, an established product in Europe both in Acromegaly and in NET with 55% SSA market share in France and 32% SSA market Share in G5
- Ramping up acromegaly sales in the US with only 2.4% SSA long acting market share in 2010

## ... exceeding 1.6 billion euros in 2020, driven by NET

### NET incidence over 30 years

Incidence per 100,000 for NET between 1973 - 2004<sup>2</sup>



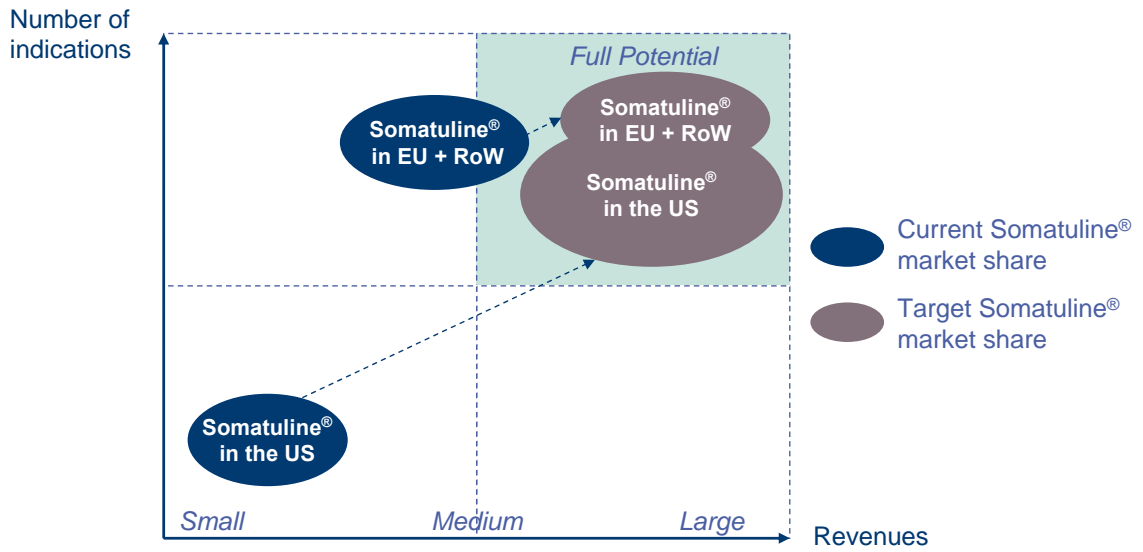
### Steady 3.8%<sup>1</sup> CAGR until 2020

- 2020 SSA market: ~€1.6bn<sup>1</sup> (+ 45% or 3.8% CAGR)

Growth in the SSA market mainly driven by:

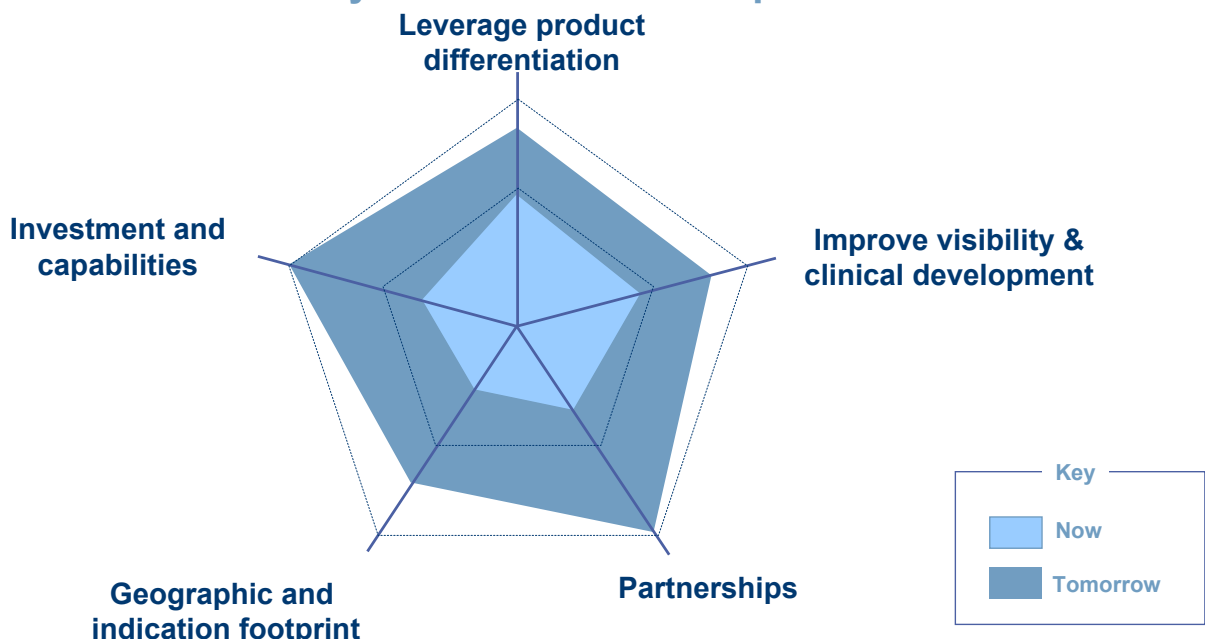
- NET
  - Studies suggest that NET incidence has been growing rapidly over the past several decades, particularly in the US
  - Increased awareness of NETs results in a wider availability of improved diagnostic techniques
- The US
  - +4.6%<sup>1</sup> expected market growth in the US between 2010-2020 (world most solid growth)

## Great potential lies ahead for Somatuline® ...



*... while SSA market is expected to grow 3.8% CAGR until 2020*

## Ipsen to work on key levers to reach full potential



*NET and the US : two main growth drivers*

## New additional elements of differentiation

### Increased extended dosing interval worldwide

- Approved in the US in March 2011
- From one injection every 4 weeks (60-90mg) to every 6-8 weeks (120mg)
- Increased comfort for the patients
- Economic benefit

### New device

- Retractable needle to ensure full dose release
- Optimal safety for hospital care practitioners/ patients
- Health economic benefits related to absence of clogging and no need for reconstitution



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## Partnerships to explore new treatment paradigm

**Innovative partnership with Pfizer Europe in Neuro Endocrine Tumors (NET)**

**Medical education initiative kicked off at ENETS  
(joint symposium on March 11th 2011 in Lisbon)**



*Build upon respective best-in-class position to develop medical education on gastro-entero-pancreatic NET (GEP NET) management*

*Drive guidance on patients profiles who would benefit most from both agents*

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## New indications: Functioning NET in the US and Non Functioning NET worldwide

### Functioning NET for US label

- Recruitment target: 100 patients
- Global recruitment status on target for completion end of 2012
- Carcinoid syndrome initially slow to recruit due to trial design and ongoing competitive trials
- 12 countries planned (US + 11 ROW countries), 66 sites (56 Row + 10 US)

USA	
▪ Brazil	▪ Russia
▪ Croatia	▪ Serbia
▪ Czech Rep.	▪ South Africa
▪ India	▪ Turkey
▪ Latvia	▪ Ukraine
▪ Poland	

### Non Functioning NET worldwide - CLARINET

- **RECRUITMENT COMPLETED** end of April 2011
- 200 patients accrued (45 centers in 14 countries)

▪ Austria	▪ Italy
▪ Belgium	▪ Poland
▪ Czech Rep.	▪ Slovakia
▪ Denmark	▪ Spain
▪ France	▪ Sweden
▪ Germany	▪ UK
▪ India	▪ US

**Somatuline<sup>®</sup>, potentially the only SSA with functioning and non-functioning NET label**

## Somatuline<sup>®</sup> Autogel 2020: a globalized reach

Geography/ Indication	Europe	US	China	Brazil	Russia
<b>Acromegaly</b>	✓	✓	✓	✓	✓
<b>Functioning NET</b>	✓	✓	-	✓	✓
<b>Non functioning NET</b>	✓	✓	-	✓	✓

✓ Ipsen presence

**LatAm and Asia covered through partnerships**



## Zoom on

# Neurology/ Dysport®

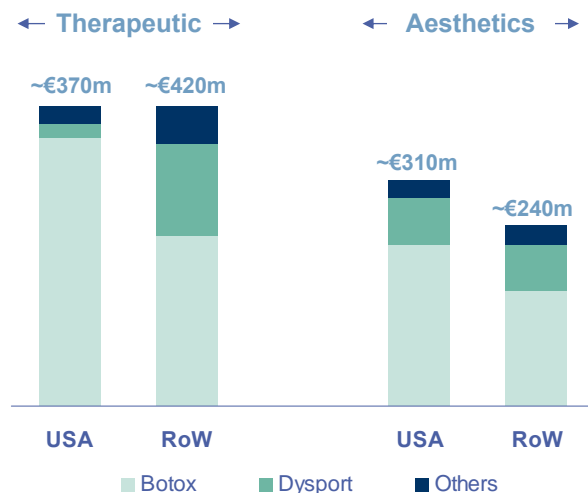


## A 2010 botulinum toxin market in excess of 1.3 billion euros

### Dysport® market metrics

- 2010 Botulinum toxin market : ~€1.35bn<sup>1</sup>
- The US represent north of 50% of the market
- Therapeutic indications represent 58% of the market
- Dysport®, a solid second player
- Dysport® recently launched by Ipsen in the USA (November 2009) with a single medical indication (cervical dystonia) and by Medecis in aesthetics (Glabellar lines)

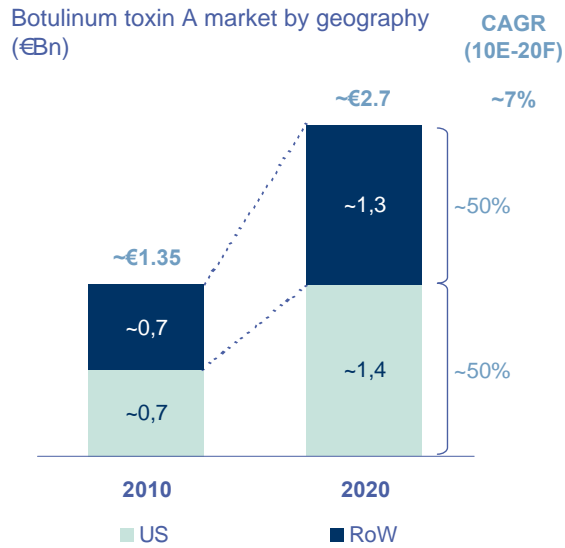
### 2010 BonTA market figures



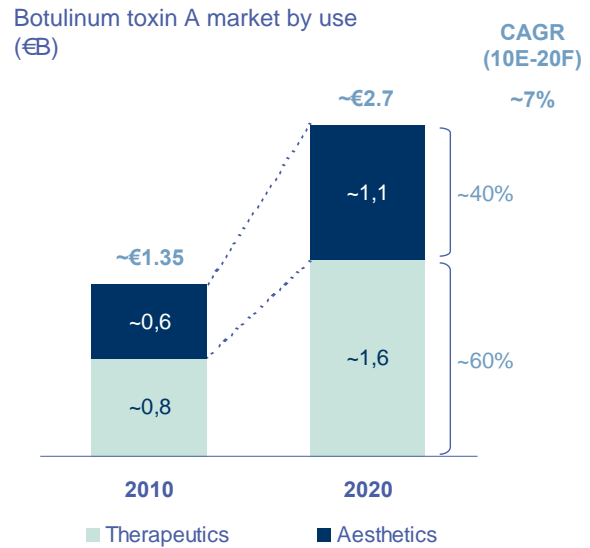
Note 1 : Internal company data

## Botulinum toxin market expected to grow by ~7% p.a. to 2.7 billion euros in ten years

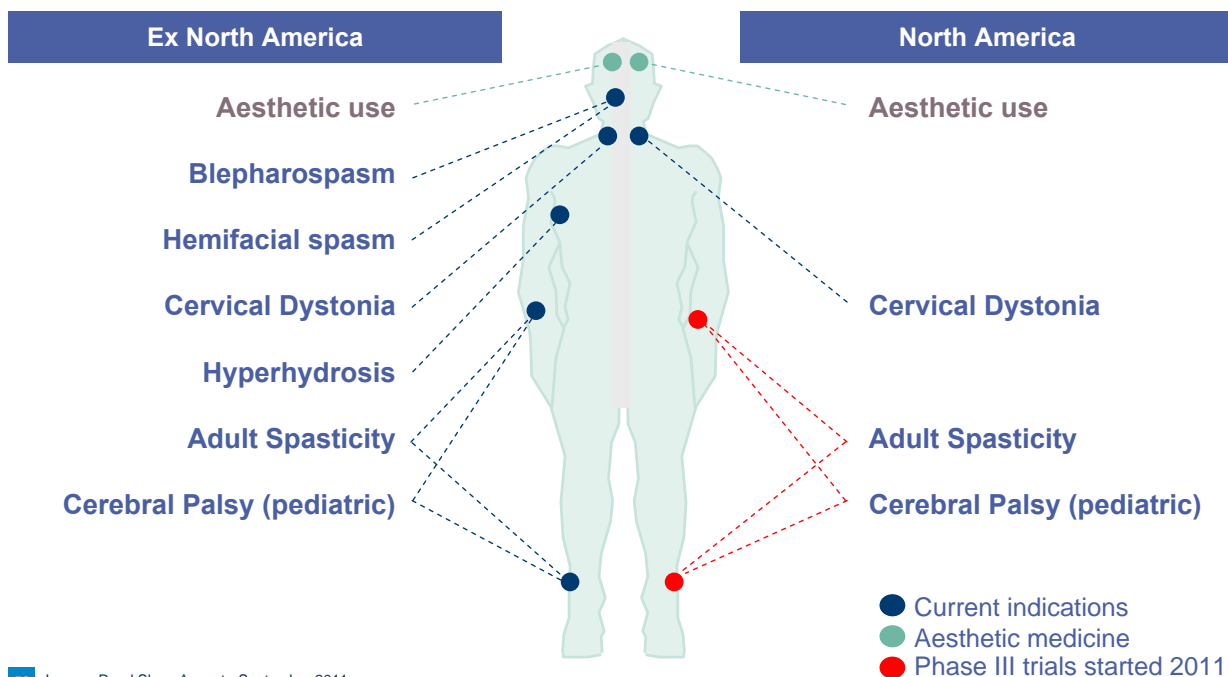
### US to remain half of 2020 WW market ...



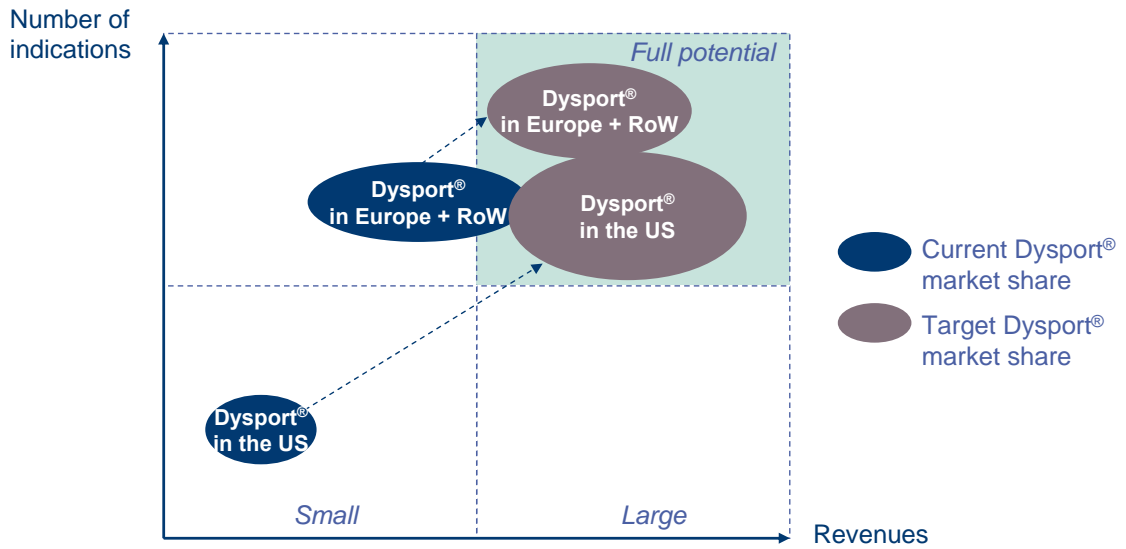
### ...with split between therapeutics and aesthetics remaining stable



## Room for new indications in North America

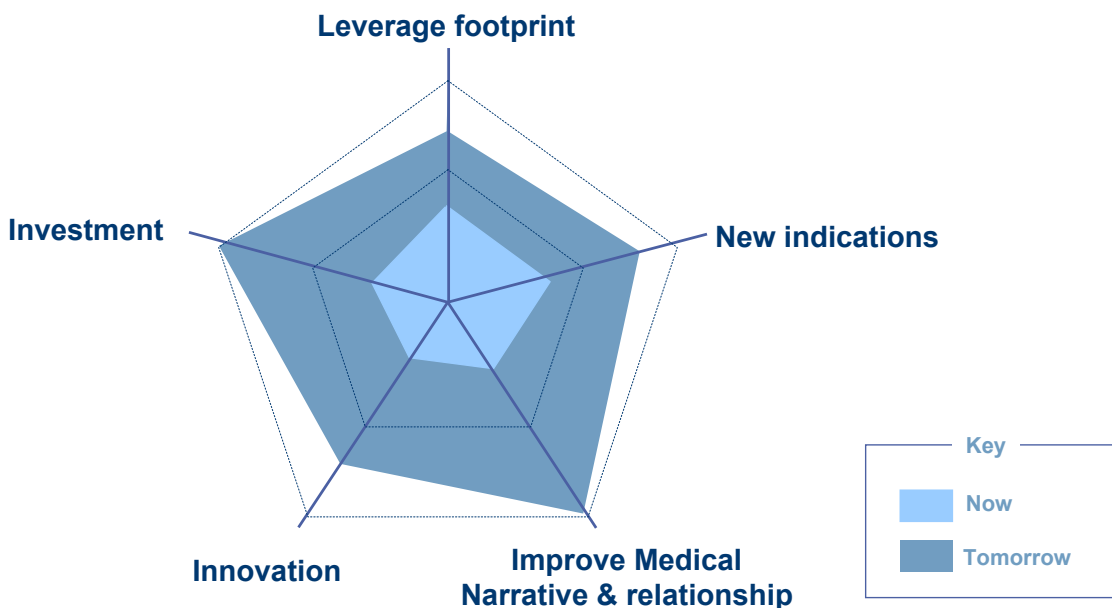


## Full potential of Dysport® lies ahead...



... and BonTA market is expected to grow 7% CAGR until 2020

## Ipsen to work on key levers to reach full potential



Spasticity and the US : two main growth drivers

## Dysport® 2020 footprint aspiration : More geographies, more indications

Geography/ Therapeutic area	Europe	US	China	Brazil	Russia
<b>Therapeutic</b>	<ol style="list-style-type: none"> <li>1.Cervical Dystonia</li> <li>2.Adult arm spasticity</li> <li>3.Blepharospasm</li> <li>4.Hemifacialspasm</li> <li>5.Paediatric per equinus spasticity (Cerebral palsy)</li> <li>6.Adult leg spasticity (in three EU markets)</li> <li>7.Hyperhidrosis</li> <li>8.Pediatric arm spasticity</li> <li>9.Neurogenic Detrusor Over-activity</li> </ol>	<ol style="list-style-type: none"> <li>1.Cervical Dystonia</li> <li>2.Adult Upper Limb</li> <li>3.Adult Lower Limb</li> <li>4.Pediatric Lower Limb</li> <li>5.Pediatric Upper Limb</li> <li>6.Neurogenic Detrusor Over-activity</li> </ol>	<ol style="list-style-type: none"> <li>1.Cervical Dystonia</li> <li>2.Other indications under assessment</li> </ol>	<ol style="list-style-type: none"> <li>1.Cervical Dystonia</li> <li>2.Adult arm spasticity</li> <li>3.Blepharospasm</li> <li>4.Hemifacialspasm</li> <li>5.Paediatric per equinus spasticity (Cerebral palsy)</li> <li>6.Adult leg spasticity</li> <li>7.Hyperhidrosis</li> <li>8.Pediatric Upper Limb</li> <li>9.Neurogenic Detrusor Over-activity</li> </ol>	<ol style="list-style-type: none"> <li>1.Cervical Dystonia</li> <li>2.Adult arm spasticity</li> <li>3.Blepharospasm</li> <li>4.Hemifacialspasm</li> <li>5.Paediatric per equinus spasticity (Cerebral palsy)</li> <li>6.Hyperhidrosis</li> <li>7.Pediatric Lower Limb</li> <li>8.Pediatric Upper Limb</li> <li>9.Neurogenic Detrusor Over-activity</li> </ol>
<b>Aesthetic</b>	<ol style="list-style-type: none"> <li>1.Glabellar Lines</li> <li>2.Canthal Lines</li> </ol>	<ol style="list-style-type: none"> <li>1.Glabellar Lines</li> <li>2.Canthal Lines</li> </ol>	<ol style="list-style-type: none"> <li>1.Glabellar Lines</li> </ol>	<ol style="list-style-type: none"> <li>1.Glabellar Lines</li> </ol>	<ol style="list-style-type: none"> <li>1.Glabellar Lines</li> </ol>

## New indications: Focus on spasticity and urology indications

### Focus on spasticity in the short term...

- Current spasticity indications:
  - Adult upper (ex-US) and lower limb (limited markets)
  - Pediatric lower limb (ex-US)
- Spasticity, a major short-term growth opportunity:
  - Stroke : 15 million people worldwide every year. 5 million are left permanently disabled<sup>1</sup>
- World-wide Adult and Pediatric Ph III program (4 trials):
  - 4 new indications in the US
  - New and/ or Improved labeling ex-US

### ... and in urology in the longer term

- Leverage current access to prescriber base:
  - Clear synergies with Uro-oncology franchise in Europe
  - Clear WW synergies with neuro-rehabilitation environment
- Neurogenic Detrusor Overactivity: Ph IIa started (NCT01357980):
  - First patient screened in May 2011
  - Limited cost and high probability of success
- Urology indications, a significant mid term growth potential

## Dysport® Next Generation: a potential new exciting opportunity

### The first ready-to-use toxin A...

- ...is a breakthrough innovation bringing clear differentiation vs. competitors
- ...saves time by avoiding reconstitution
- ...improves safety (dilution/dosage, reconstitution, single use product ...)
- ...has very positive qualitative and quantitative market research results<sup>1</sup> (c. 500 participants) :
  - 83% of potential adopters on time saving and improved safety grounds

### A potentially transforming project

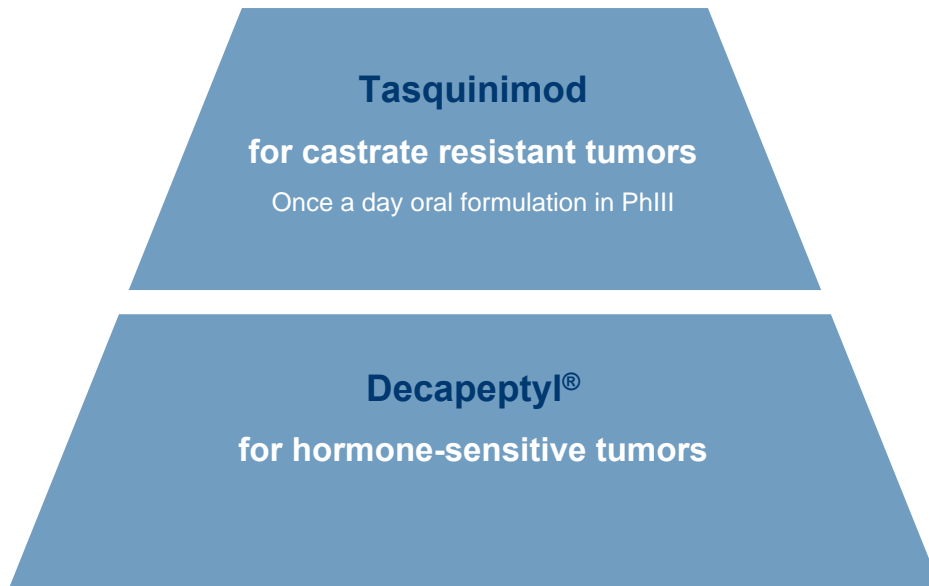
- A WW Ph III program to assess safety and efficacy:
  - Indication : Cervical Dystonia
  - 350 patients
  - 71 sites (42 in Europe, 29 in the US)
  - First patients recruited in Europe
  - US recruitment pending feedback from FDA in Q3 2011
- A complex manufacturing process with technical hurdles to be addressed
- Ipsen team fully mobilized to bring R&D project to fruition

*Potentially, a major change in market paradigm*

## Zoom on

## Uro-Oncology/ Decapeptyl®

## A franchise with renewed growth opportunities

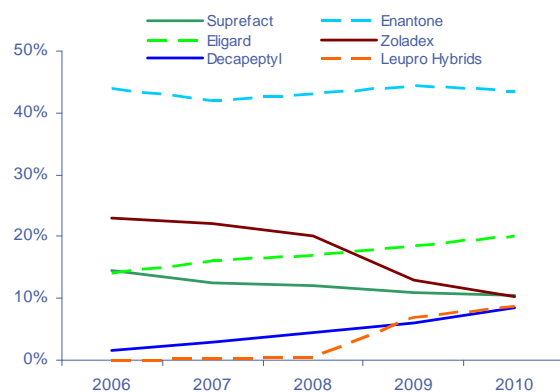


## No true generics of GnRH analogs anticipated, only Hybrids

### Hybrids rather than true generics

- Risk of true long acting GnRH analogs generics entry expected to be low
- Only hybrids of leuprorelin are available today<sup>1</sup>
- Hybrids are currently not substitutable and priced 20-25% below original products
- In Germany, the 2 leuprorelin hybrids have reached less than 10% MS in 3 years<sup>2</sup> with no impact on class price yet

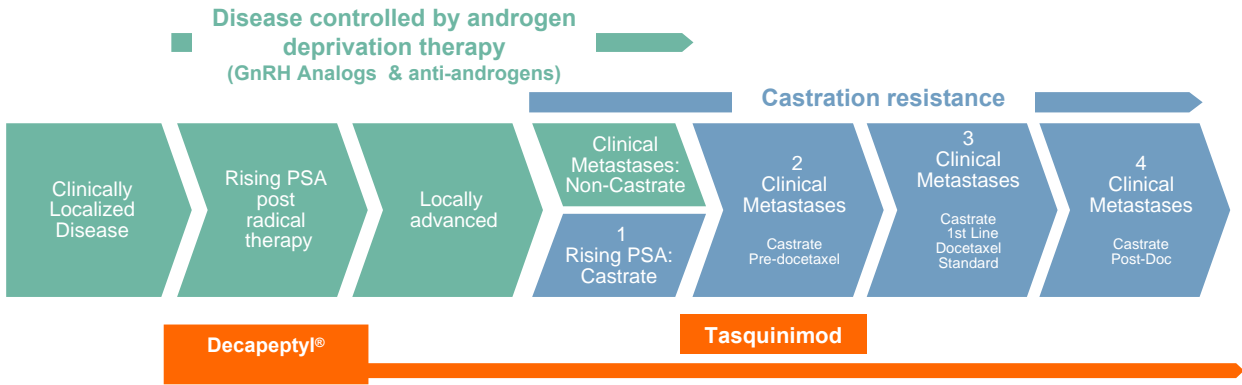
### Impact of hybrids on market shares MEU (\*) in Germany



(\*) MEU = Monthly equivalent units  
Source: Insight Health, OdV data - Germany

### Hybrids represent a moderate threat to GnRH established brands compared to true generics

## Tasquinimod: a perfect strategic fit



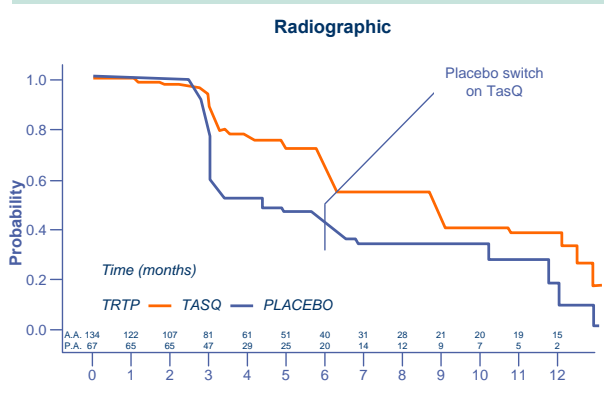
Population Incidence in G5*	149 000 Stage I & II	111 000 Stage III & IV	153 000 CRPC
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- Leverage the Group's current leadership position in prostate cancer
- Expand to medical oncology
- Access to significant sales potential
- Beyond prostate, tasquinimod has potential in other cancers (such as GI)

## Tasquinimod, promising phase II results

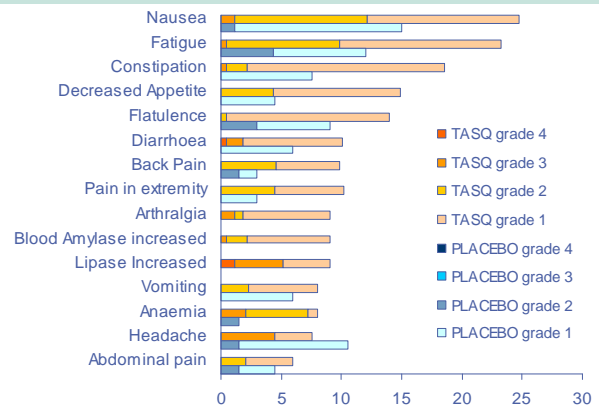
**Safety and efficacy analysis\* of Phase II study of Tasquinimod in chemotherapy naïve patients with asymptomatic metastatic castrate-resistant prostate cancer (CRPC) (n=201)**

**Primary end point**  
Proportion of patients with progression at 6 months:  
**n=134/67 31% in Tasquinimod group vs. 66% in placebo group**



**Tasquinimod improves Radiographic Progression Free survival vs. placebo (8.8 months vs. 4.4 months)**

**Most common AE-s and percent of patients with grade 1-4 in Double-blind phase**



**Side effects are manageable**

\* ASCO-GU, 2011, J. Armstrong<sup>1</sup>, M. Haggmar<sup>2</sup>, W. M. Stadler<sup>3</sup>, J. R. Gingrich<sup>4</sup>, V. J. Assikis<sup>5</sup>, O. Nordle<sup>6</sup>, G. Forsberg<sup>6</sup>, M. A. Carducci<sup>7</sup>, R. Pil<sup>8</sup>



## Tasquinimod, Phase III program ongoing

**A Phase III randomized, double-blind, placebo-controlled study of Tasquinimod in men with asymptomatic/mildly asymptomatic Metastatic Castrate Resistant Prostate Cancer**

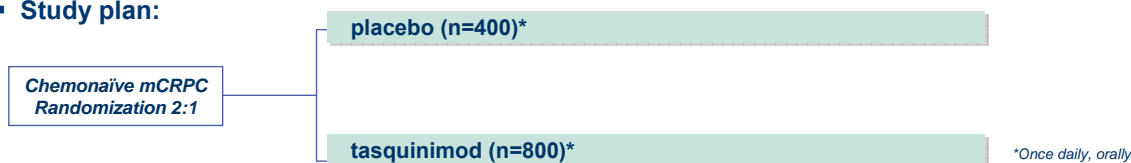
▪ **Objectives**

- TASQ in chemo-naïve patients with metastatic castrate-resistant prostate cancer
- Effect of Tasquinimod on delaying disease progression compared with placebo

▪ **Endpoints**

- Primary: Radiological progression-free survival (PFS)
- Secondary Endpoint: Overall Survival (OS) – Study powered for OS

▪ **Study plan:**



▪ **Principal investigators:**

- America : Michael A Carducci, Johns Hopkins Kimmel Cancer Center, Baltimore, USA
- Europe : Cora N Sternberg, San Camillo and Forlanini Hospitals – Rome, Italy

*International Pivotal Phase III opened 1Q 2011...*

*... filing expected in 2014*



## Tasquinimod, deal terms for Ipsen

**Geographies**

- World excluding Japan and the Americas

**Execution**

- Active Biotech: Pivotal registration PhIII
- Ipsen: Supportive study

**Financials**

- Milestones :
  - Upfront payment of €25 million
  - Additional payments of €175 million contingent upon progress/ achievement of clinical, regulatory and commercial milestones
- Royalty rate: progressive on the level of sales starting in the low teens

**Expected peak sales: in excess of €250m**



**Zoom on:**

## **Hemophilia**



**Ipsen and Inspiration are aiming at all levels of the coagulation cascade for the treatment of hemophilia**

**A full fledged hemophilia franchise, with potentially 4 products**

**...with a broad potential inhibitor therapy offering (OBI-1, FVIIa)...**

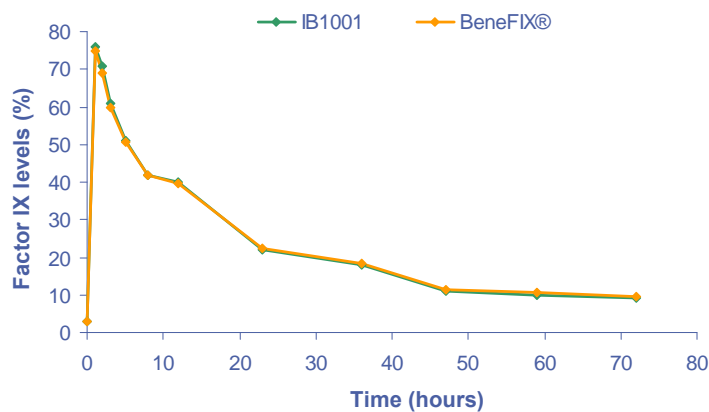
**...and the first recombinant competitor in hemophilia B therapy, IB1001**

**...differentiated with OBI-1, the only recombinant porcine FVIII product...**

- An \$8bn market
- A high margin market
- 2 products in Ph III:
  - OBI-1: a highly innovative porcine recombinant Factor VIII (orphan drug)
  - IB1001: first rFIX biosimilar in an underserved, fast growing market

## IB 1001 demonstrated non-inferiority to BeneFIX®

### Mean FIX activity by time and treatment



The preliminary safety data collected during the PK study phase indicate that IB1001 has an acceptable safety profile and is well tolerated

Study IB1001-01 is ongoing and further analyses on safety and efficacy will be available in 2011.

## Ipsen now has ~34% of fully diluted ownership of Inspiration

